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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,849	01/13/2006	Dorian Bevec	ARTHP1116US	2217
23623 7590 06/13/2007 AMIN, TUROCY & CALVIN, LLP 1900 EAST 9TH STREET, NATIONAL CITY CENTER 24TH FLOOR, CLEVELAND, OH 44114			EXAMINER BRADLEY, CHRISTINA	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 06/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/564,849	BEVEC, DORIAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/19/06, 6/5/06, 1/13/06</u> . | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

1. Applicant's election with traverse of SEQ ID NO: 4 and idiopathic pulmonary fibrosis in the reply filed on 4/2/2007 is acknowledged. The traversal is on the ground(s) that it would not be a burden to search additional sequences or diseases. This is not found persuasive because each sequence and disease requires a separate search query. The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112/101***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 provide for the use of a peptide comprising SEQ ID NO: 4, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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6. Claims 1-18 are being interpreted as pharmaceutical composition claims for the purposes of examination.

***Claim Rejections - 35 USC § 112***

7. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

8. In claim 2, the use of the semicolon without a conjunction renders the claim indefinite.

Does the polypeptide contain SEQ ID NOs: 14 and 13 or SEQ ID NOs: 14 or 13?

9. In claim 3, there is a lack of antecedent basis for n, m. The use of the comma without a conjunction renders the claim indefinite. The formula presented in the claim does not include the numbers 0-25; what is n, m replacing?

10. In claim 4, there is a lack of antecedent basis for X,Y and for o,p. The use of the comma without a conjunction renders the claim indefinite. The formula presented in the claim does not include the numbers 0-11; what is o,p replacing?

11. In claim 5, there is a lack of antecedent basis for X',X'' and for o,p. The use of the comma without a conjunction renders the claim indefinite. The formula presented in the claim does not include the numbers 0-4; what is r,q replacing?

12. In claim 6, there is a lack of antecedent basis for  $X^1$ - $X^{22}$  due to the use of the singular verb to be.

***Claim Rejections - 35 USC § 102***

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13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Block (WO 02/43746, cited on Information Disclosure Statement filed 1/13/2006). Block teaches pharmaceutical compositions comprising the peptide HSDAVFTDNYTRLRKQMAVKKYLNSILN (VIP, SEQ ID NO: 1) for the treatment of pulmonary hypertension and related disorders. With respect to claim 2, the peptide comprises both SEQ ID NOs: 13 and 14. With respect to claim 3, n is 13 and m is 5. With respect to claim 4, (A)<sub>n</sub> contains the sequence FTD with o equal to 5 and p equal to 5. With respect to claim 5, (X)<sub>o</sub> contains HSD with q equal to 0 and r equal to 3. With respect to claim 6, the peptide is SEQ ID NO: 1, option viii and SEQ ID NO: 11, option vii. With respect to claim 8, Block teaches that the peptide can be in a stabilized form (page 10, lines 20-34). With respect to claims 12, 15 and 18, the peptide is in aerosol form (Examples 1-5). With respect to the limitations regarding the disease or condition to be treated, MPEP § 2112.02 states: “when the claim recites using an old composition or structure and the “use” is directed to a result or property of that composition or structure, then the claim is anticipated.”

#### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

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application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

16. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No.

10/501,660. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to pharmaceutical compositions comprising peptides containing the sequence RKQMAVKKYL. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No.

10/517,125. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to pharmaceutical compositions comprising peptides containing the sequence RKQMAVKKYL. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571)

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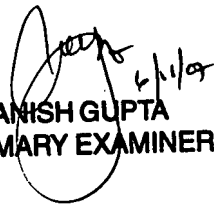
272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Marchetti Bradley, Ph.D.  
Patent Examiner  
Art Unit 1654

cmb

  
**ANISH GUPTA**  
**PRIMARY EXAMINER**